

**Remarks/Arguments**

Reconsideration of the above-identified application in view of the present amendment is respectfully requested.

By the present amendment, claims 1, 7, 12, 15, 22, and 25 are amended. Claims 6, 16, 17, 33-35, and 42-45 are cancelled. Hence, claims 1-5, 7-15, 18-32 and 36-41 are pending in the application.

Applicants respectfully acknowledge Examiner's consideration of Applicants' arguments and amendments filed July 14, 2005, and wish to thank the Examiner for the indication of allowability of claims 9-11, 17-19, 23 and 24, as well as the allowance of claims 29-32 and 36-41.

**Rejection under 35 U.S.C. §112**

The Examiner rejected claims 22-24 under 35 U.S.C. §112, second paragraph, as being indefinite. Specifically, claims 22-24 were rejected because claims 22 lacks antecedent basis for "the disk" in line 7. Claim 22 has been amended to overcome this rejection. Claims 23-24 depend from claim 22, and thus the rejection to claims 23-24 has likewise been overcome.

**Rejection under 35 U.S.C. §102(e) by U.S. Patent Publication No. US 2005/0004637**

The Examiner rejected claims 1, 7, 8, 12, 13, 15, 16, 20-22, 25-28, 33-35, and 42-45 as being anticipated by U.S. Patent Publication No. 2005/0004637 to Singhal et al. (hereinafter "Singhal"). Claims 16, 33-35, and 42-45 have been cancelled and thus will not be addressed. It is respectfully submitted that claim 1, as amended, patentably defines over Singhal, and is therefore allowable.

As amended, claim 1 recites a lead retainer extending from the burr hole ring, the lead retainer being configured to releasably retain a plurality of distinct sections of the excess portion of the lead.

Singhal does not teach a lead retainer configured to retain a plurality of distinct sections of the excess portion of the lead. Rather, Singhal teaches a burr hole cap 140 comprising a ring member 142 and a cover member 144 (¶ 63). The ring member 142 includes the groove 146 which receives a lead 148. The surgeon can coil the lead 148 inside groove 146, and draw lead 148 through exit 150 (¶ 64 and Fig. 8). That is, Singhal teaches a groove 146 that retains a single continuous section of the lead wire 148 that enters the groove 146 from the burr hole, coils around the groove, and exits through the exit 150, and not a plurality of distinct sections of the lead, as recited in amended claim 1. No portion of the single section of the lead wire 148 retained in the groove 146 is distinct from any other portion. Since Singhal does not teach or suggest a lead retainer configured to retain a plurality of distinct sections of the excess portion of the lead, as recited by amended claim 1, it is respectfully submitted that claim 1, as amended, patentably defines over Singhal, and is therefore allowable.

Claims 7 and 8 depend from claim 1 and are allowable for at least the same reasons claim 1 is allowable, and for the specific limitations recited therein.

As amended, claim 12 recites a flange extending from a sleeve, the flange having means for at least partially retaining a plurality of distinct sections of the excess portion of the lead.

As noted with respect to claim 1, Singhal does not teach a flange for partially retaining a plurality of distinct sections of the excess portion of the lead. Singhal teaches a groove 146 that retains a single continuous section of the lead wire 148 that enters groove 146 from the burr hole, coils around the groove, and exits through the exit 150, and not a plurality of distinct sections of the lead, as recited in amended claim 12. No portion of the single section of the lead wire 148 retained in the groove 146 is distinct from any other portion. Since Singhal does not teach or suggest a flange having means for at least partially retaining a plurality of distinct sections of an excess portion of the lead, as recited by amended claim 12, it is respectfully submitted that claim 12, as amended, patentably defines over Singhal, and is therefore allowable.

Claim 13 depends from claim 12 and is allowable for at least the same reasons claim 12 is allowable, and for the specific limitations recited therein.

Amended claim 15 incorporates the combined features of cancelled claims 16 and 17. Previous claim 17 was objected to as being dependent upon a rejected base claim, but was indicated as being allowable if rewritten in independent form. Therefore, the inclusion of the subject matter of previous claim 17 into independent claim 15 renders amended claim 15 allowable.

Claims 20 and 21 depend from claim 15 and are allowable for at least the same reasons claim 15 is allowable, and for the specific limitations recited therein.

As amended, claim 22 recites at least one lead retainer extending from a ring to store a plurality of distinct sections of the excess portion of the lead.

As noted with respect to claim 1, Singhal does not teach at least one retainer to store a plurality of distinct sections of the excess portion of the lead. Singhal teaches a groove 146

that retains a single continuous section of the lead wire 148 that enters the groove 146 from the burr hole, coils around the groove, and exits through the exit 150, and not a plurality of distinct sections of the lead, as recited in amended claim 22. No portion of the single section of the lead wire 148 retained in the groove 146 is distinct from any other portion. Since Singhal does not teach or suggest at least one lead retainer extending from a ring to store a plurality of distinct sections of the excess portion of the lead, as recited by amended claim 22, it is respectfully submitted that claim 22, as amended, patentably defines over Singhal, and is therefore allowable.

As amended, claim 25 recites at least one lead retainer extending radially outward from the disk to store a plurality of distinct sections of the excess portion of the lead.

As noted with respect to claim 1, Singhal does not teach at least one lead retainer to store a plurality of distinct sections of the excess portion of the lead. Singhal teaches a groove 146 that retains a single continuous section of the lead wire 148 that enters the groove 146 from the burr hole, coils around the groove, and exits through the exit 150, and not a plurality of distinct sections of the lead, as recited in amended claim 25. No portion of the single section of the lead wire 148 retained in the groove 146 is distinct from any other portion. Since Singhal does not teach or suggest at least one lead retainer extending radially outward from the disk to store a plurality of distinct sections of the excess portion of the lead, as recited by amended claim 25, it is respectfully submitted that claim 25, as amended, patentably defines over Singhal, and is therefore allowable.

As amended, claim 26 recites the step of inserting a plurality of distinct sections of the excess portion of the lead into the lead retainer to retain the lead.

Singhal does not teach the step of inserting a plurality of distinct sections of the lead into the lead retainer. Singhal teaches the step of coiling the lead 148 inside the groove 146 (¶ 64). As shown in Fig. 8, the coil of the lead 148 is a single, continuous section of the lead. Once the lead 148 is fed through the burr hole and opening in the burr hole cap 140, the lead 148 is wound around the groove 146 and subsequently exits the groove 146 through exit 150 (Fig. 8). That is, the practitioner does not insert a plurality of distinct sections into the groove; but instead coils a single continuous section of the lead 148 around the groove. Since Singhal does not teach or suggest the step of inserting a plurality of distinct sections of the excess portion of the lead into the lead retainer to retain the lead, as recited in amended claim 26, it is respectfully submitted that claim 26, as amended, patentably defines over Singhal, and is therefore allowable.

Claims 27 and 28 depend from claim 26 and are allowable for at least the same reasons claim 26 is allowable, and for the specific limitations recited therein.

**Rejection Under 35 U.S.C. §102(e) by U.S. Patent No. 7,004,948**

The Examiner rejected claims 1-5, 7, 8, 12, 14-16, 20-22, 25-28, 33-35, and 42-45 as being clearly anticipated by U.S. Patent No. 7,004,948 to Pianca et al. (hereinafter "Pianca"). Claims 16, 33-35, and 42-45 have been cancelled and thus will not be addressed. It is respectfully submitted that as amended, claim 1 patentably defines over Pianca, and is therefore allowable.

As amended, claim 1 recites a lead retainer extending from the burr hole ring, the lead retainer being configured to releasably retain a plurality of distinct sections of the excess portion of the lead.

Pianca does not teach a lead retainer configured to retain a plurality of distinct sections of the excess portion of the lead. Pianca teaches a burr hole plug assembly 54 having a hole cavity 56 and a plug cap 58. The plug cap enable wrapping excess lead length 30' in the hole cavity 56 of the burr hole plug assembly 54. The external end 31 of the lead 30 is attached to the cap 58. The cap 58 is then rotated, which causes the lead length 30' to be coiled within the hole cavity 56 (Col. 8, line 62 to Col. 9, line 2 and Fig. 8A). That is, Pianca teaches a single continuous length 30' of lead 30 that is retained within the cavity 56, not a plurality of distinct sections of the excess portion of the lead, as recited in amended claim 1. No portion of the single section of the lead length 30' retained in the chamber 56 is distinct from any other portion. Since Pianca does not teach or suggest a lead retainer configured to retain a plurality of distinct sections of the excess portion of the lead, as recited by amended claim 1, it is respectfully submitted that claim 1 patentably defines over Pianca, and is therefore allowable.

Claim 2 recites that the lead retainer is connected to the burr ring by an integral living hinge. Pianca does not teach a living hinge. Pianca teaches a burr hole plug assembly 54 having a hole cavity 56 and a plug cap 58. The hole cavity 56 is defined by what appears to be a continuous, circular wall (Fig. 8A). The wall acts as both a lead retainer on its inner surface and a burr hole ring on its outer surface. That is, the lead retainer is also the burr ring; they are not connected by anything and, thus there is no integral living hinge between them. Since Pianca does not teach or suggest that the lead retainer is connected to the burr ring by an integral living hinge it is respectfully submitted that claim 2 patentably defines over Pianca, and is therefore allowable.

Claim 3 recites that the integral living hinge permits relative movement between the lead retainer and the burr hole ring between expanded and collapsed positions.

Pianca does not teach that the lead retainer and the burr hole ring can move relative to each other. Pianca teaches a burr hole plug assembly 54 having a hole cavity 56 and a plug cap 58. The burr hole plug assembly can be used to seal a burr hole made in the patient's skull (Col. 6, lines 48-50). The plug cap 58 enables wrapping excess lead length 30' in the hole cavity 56 of the burr hole plug assembly 54 (Col. 8, lines 62-65 and Fig. 8A), which is subsequently placed within the burr hole. The hole cavity 56 is defined by what appears to be a continuous, circular wall (Fig. 8A). The wall acts as both a lead retainer on its inner surface and a burr hole ring on its outer surface. Therefore, there can be no relative movement between the lead retainer and the burr hole ring. Since Pianca does not teach or suggest that the lead retainer and the burr hole ring can move relative to each other, claim 3 patentably defines over Pianca, and is therefore allowable.

Claim 4 recites that the retainer is pivotally connected to the burr ring. As noted above with respect to claim 3, the wall defining the hole cavity 56 acts as both a lead retainer on its inner surface and a burr hole ring on its outer surface. Therefore, there can be no pivotal connection between the lead retainer and the burr hole ring. Since Pianca does not teach or suggest that a retainer is pivotally connected to the burr ring, claim 4 patentably defines over Pianca, and is therefore allowable.

Claim 5 recites a pivot hinge that selectively enables the lead retainer to move between expanded and collapsed positions. Pianca does not teach a lead retainer that moves between expanded and collapsed positions. Pianca teaches a hole cavity 56 defined by what appears to be a continuous, circular wall (Fig. 8A). The lead length 30' is retained within cavity 56

(Fig. 9B) after the hole plug assembly 54 is placed within the burr hole of the skull. Thus, the hole cavity does not include a pivot hinge that selectively enables the lead retainer to move between expanded and collapsed positions. Rather, it is a single, rigid object that remains in the same position once implanted in the skull. Since Pianca does not teach or suggest the subject matter of claim 5, it is respectfully submitted that claim 5 is allowable.

Claims 7 and 8 depend from claim 1 and are allowable for at least the same reasons claim 1 is allowable, and for the specific limitations recited therein.

As amended, claim 12 recites a flange extending from a sleeve, the flange having means for at least partially retaining a plurality of distinct sections of the excess portion of the lead.

As noted with respect to claim 1, Pianca does not teach a flange for partially retaining a plurality of distinct sections of the excess portion of the lead. Pianca teaches a single continuous length 30' of lead 30 that is retained within cavity 56, not a plurality of distinct sections of the excess portion of the lead, as recited in amended claim 12. No portion of the single section of the lead 30 retained in the chamber 56 is distinct from any other portion. Since Pianca does not teach or suggest a flange having means for at least partially retaining a plurality of distinct sections of an excess portion of the lead, as recited by amended claim 12, it is respectfully submitted that claim 12 patentably defines over Pianca, and is therefore allowable.

Claim 14 recites that the retaining means includes a plurality of tabs extending from an outside surface of the flange, the tabs configured to form a groove between adjacent tabs to thereby form a plurality of grooves to retain the plurality of different sections of the excess portion of the lead.



Pianca does not teach a plurality of tabs that form a plurality of grooves to retain the plurality of different sections of the lead. Pianca teaches a hole cavity 56 defined by what appears to be a continuous, circular wall (Fig. 8A). The hole cavity 56 retains a length 30' of lead 30. That is, the single length 30' of lead 30 is retained within the single circular wall defining cavity 56, not within a plurality of grooves defined by a plurality of tabs extending from an outside surface of a flange. Since Pianca does not teach or suggest that the retaining means includes a plurality of tabs extending from an outside surface of the flange, the tabs configured to form a groove between adjacent tabs to thereby form a plurality of grooves to retain the plurality of different sections of the excess portion of the lead, as recited by claim 14, it is respectfully submitted that claim 14 patentably defines over Pianca, and is therefore allowable.

As amended, claim 22 recites at least one lead retainer extending from a ring to store a plurality of distinct sections of the excess portion of the lead.

As noted with respect to claim 1, Pianca does not teach a lead retainer to store a plurality of distinct sections of the excess portion of the lead. Pianca teaches a single continuous length 30' of lead 30 that is retained within cavity 56, not a plurality of distinct sections of the excess portion of the lead, as recited in amended claim 22. No portion of the single section of the lead 30 retained in the chamber 56 is distinct from any other portion. Since Pianca does not teach or suggest at least one lead retainer extending from a ring to store a plurality of distinct sections of the excess portion of the lead, as recited by amended claim 22, it is respectfully submitted that claim 22 patentably defines over Pianca, and is therefore allowable.

As amended, claim 25 recites at least one lead retainer extending radially outward from the disk to store a plurality of distinct sections of the excess portion of the lead.

As noted with respect to claim 1, Pianca does not teach a lead retainer to store a plurality of distinct sections of the excess portion of the lead. Pianca teaches a single continuous length 30' of lead 30 that is retained within cavity 56, not a plurality of distinct sections of the excess portion of the lead, as recited in amended in claim 25. No portion of the single section of the lead 30 retained in the chamber 56 is distinct from any other portion. Since Pianca does not teach or suggest at least one lead retainer extending radially outward from the disk to store a plurality of distinct sections of the excess portion of the lead, as recited by amended claim 25, it is respectfully submitted that claim 25 patentably defines over Pianca, and is therefore allowable.

As amended, claim 26 recites the step of inserting a plurality of distinct sections of the excess portion of the lead into the lead retainer to retain the lead.

Pianca does not teach the step of inserting a plurality of distinct sections of the lead into the lead retainer. Pianca teaches attaching the external end 31 of lead 30 to cap 58 and rotating the cap 58 as shown by arrow 60 in Fig. 8A, which causes the lead length 30' to be coiled within the hole cavity 56. That is, the practitioner does not insert a plurality of distinct sections of lead 30 into the cavity 56; he coils a lead length 30' within the hole cavity 56 (Col. 8, line 62 to Col. 9, line 2 and Fig. 8A). Since Pianca does not teach or suggest the step of inserting a plurality of distinct sections of the excess portion of the lead into the lead retainer to retain the lead, as recited in amended claim 26, it is respectfully submitted that claim 26 patentably defines over Pianca, and is therefore allowable.

Claims 27 and 28 depend from claim 26 and are allowable for at least the same reasons claim 26 is allowable, and for the specific limitations recited therein.

In view of the foregoing, it is respectfully submitted that the above-identified application is in condition for allowance, and allowance of the above-identified application is respectfully requested.

Please charge any deficiency or credit any overpayment in the fees for this amendment to our Deposit Account No. 20-0090.

Respectfully submitted,



Richard S. Wesorick  
Reg. No. 40,871

TAROLLI, SUNDHEIM, COVELL,  
& TUMMINO L.L.P.  
1300 East Ninth Street, Suite 1700  
Cleveland, Ohio 44114-1501  
Phone: (216) 621-2234  
Fax: (216) 621-4072  
Customer No.: 26,294